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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/509,934 05/03/00 STEINMEYER

A SCH1747

HM12/0604

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EXAMINER

QAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/509,934

Applicant(s)

Steinmeyer et al.

Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 14, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, and 8-29 is/are pending in the application.
- 4a) Of the above, claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8-11, and 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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Office Action on Merits

Status of the Application

Claims 1-29 are pending.

Claims 4 and 7 are canceled.

Claims 1-3, 5-6, 8-11 and 14-29 are rejected.

Claims 12 and 13 are withdrawn from consideration as non elected invention.

All the rejections are maintained for the same reasons as set forth in our previous office action. Applicant's arguments were fully considered but are not found persuasive. Applicant argue that prior art teaches the cyclopropyl group at 24 positioon whereas instant claims are claiming at 25-position. Examiner respectfully disagree because instant invention is claiming Q which can be alkyl group which can have OH at any position which in turn can be etherified or esterified, keto groups, amino groups or halogens (see definition of Q in claim 1).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-3, 5-6, 8-11 and 14-29 rejected under the judicially created doctrine of double patenting over claims 1-15 of U. S. Patent No. 5,585,368 and claims 1-9 of US Patent 5,700,791 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Instant invention is drawn to the vitamin D derivatives which are considered obvious over the claims of the prior US Patent issued to the same inventor and same assignee.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the

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instant application during prosecution of the application which matured into a patent. See MPEP § 804.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kersh et al. (WO 97/00242). See compound 106a and 106b on page 92 and example XXXIV on page 36 which has cyclopropyl group at C-25 position.

Claims and new claims 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirsh et al. (WO 97/00242) for the same reasons as set forth in our previous office action. See the entire document especially formula I on page 1, example XXXIV on page 36. Kirsh et al teaches 25-substituted vitamin D derivatives, their process of making and method of use.

Instant claims differ from the reference in claiming a limited genus than the prior art. A cyclopropyl ring is the only substituent at 25 position whereas prior art teaches 3-7 membered carbocyclic or heterocyclic ring and other groups at the same position.

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It would have been obvious to one skilled in the art at the time of the invention to prepare additional beneficial compounds and their compositions for medicinal use by selecting cyclopropyl ring at 25-position. This would have been obvious because 3-7 carbon cyclic rings at the same position has been taught by the prior art. Instant invention is the selection of prior art teachings. There has been ample motivation provided by the prior art to prepare the instant invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by

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the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi, Ph.D.

Primary Examiner

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